Food·Drug·Cosmetic Law

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

Robert S. Roe, Director of the Division of Program Research, Food and Drug Administration, was graduated from the University of Denver in 1924. He entered the government service as a chemist at the Chicago laboratory the following year.

In 1930, Mr. Roe was transferred to Washington, D. C., as assistant to the Chief of Import Supervision. From 1934 to 1937, he served as Assistant Chief of San Francisco Station; from 1937 to 1943, as Chief of Seattle Station; and from 1943 until August of this year, as Chief of Los Angeles District. He assumed his present position upon the retirement of James O. Clarke.

Henry A. Lepper was born in Washington, D. C., on March 27, 1889, and has continuously resided there. He received a B. S. degree in chemistry from George Washington University in June, 1913, and in December of that year received an appointment as chemist in the Bureau of Chemistry of the United States Department of Agriculture.

He was assigned to the food division, and is now Assistant Chief of that division in the FDA. Mr. Lepper's investigations have been on the composition and analysis of foods and on the development of methods of analysis, whereby data and analytical results serviceable in the enforcement of the provisions of the law as applied to foods have been developed. The results of the investigations have appeared in numerous papers in scientific journals.

From 1935 to 1943, he was editor of the *Journal of the Association of Official Agricultural Chemists;* he served as secretary of the association from 1943 to 1951; he is now its president. Since 1926, he has also been a section editor for *Chemical Abstracts,* in charge of Section 12 on foods. Mr. Lepper is a public trustee of the Food Law Institute.

A member of the Colorado and the Supreme Court bars, **Benjamin F. Stapleton, Jr.** is a partner in the law firm of Ireland, Ireland, Stapleton & Pryor, of Denver; he is also counsel for the Pure Food Manufacturing Company, of that city. He is known in the food and drug field for his work as successful counsel before the United States Supreme Court in the *Imitation Jam* case, decided in March of 1951.

Mr. Stapleton is a graduate of the University of Colorado (1939) and of the Yale Law School (1942). He served four years in the United States Naval Reserve, attaining the rank of lieutenant commander.

John L. Harvey, Associate Commissioner of Food and Drugs, is a native of Virginia, and attended William and Mary College for two years before active duty in France in World War I. He took a special course at the Beaune University in France in 1919. After the war he attended the University of Richmond and Virginia Polytechnic Institute, and studied medicine for two years at Tulane University.

Mr. Harvey entered the federal service as a food and drug inspector in January, 1925, at Seattle. From November, 1927, to June, 1930, he was a resident inspector at Salt Lake City. From June, 1930, to April, 1934, he was Assistant to the Chief of Western District. He became Chief of Seattle Station at that time, and in April, 1937, became Chief of Western District. In July, 1948, he assumed duties as Director of the Division of Litigation and in June, 1949, as Director of the Division of Regulatory Management. In June, 1951, he became an Associate Commissioner.

Before beginning his government career, Mr. Harvey was an inspector for the Virginia State Board of Health and with the United States Public Health Service. He also had two years of experience as a saleman for a chemical manufacturing concern.

Chief of New Orleans Station of the FDA since 1930, **E. C. Boudreaux** has been with the Bureau of Chemistry and the Administration for more than 30 years. He entered the service as a chemist at New Orleans Station on May 8, 1922. Upon illness and the death of the Chief of the station, he became acting Chief in September, 1924, and was appointed Chief six years later.

Mr. Boudreaux was born in Louisiana, and received his education there. He was graduated from Louisiana State University in 1918. Outside of a short period as a high school teacher, Mr. Boudreaux's activities have been in the laboratory and the administrative end of the chemistry field. He was employed as chemist by several commercial firms, including Parke, Davis & Company of Detroit; Bogalusa Paper Company, Bogalusa, Louisiana; and Penick & Ford, New Orleans.

Well known to readers of the JOURNAL is **George P. Larrick,** Deputy Commissioner of Food and Drugs. He has been a frequent contributor of excellent articles; his current one, on grain sanitation, is derived from an address before the national meeting of the Grain and Feed Dealers Association, held at Minneapolis last September.

In the Courts

FDA's Plant-Inspection Right.—On December 8, in *U. S. v. Cardiff,* the United States Supreme Court upheld an earlier decision of the United States Court of Appeals for the Ninth Circuit that any plant manager who had never before granted to the Food and Drug Administration permission to send inspectors into his private plant could continue to exclude them. The new ruling was by an eight-to-one decision. Justice Burton dissented, but without a written opinion. Justice Douglas wrote the majority opinion, with Justice Jackson concurring. In part, the opinion read:

"Respondent was convicted of violating § 301 (f) of the Food, Drug and Cosmetic Act . . . .

"The Department of Justice urges us to read § 301 (f) as prohibiting a refusal to permit entry or inspection at any reasonable time. . . .

". . . However we read § 301 (f) we think it is not fair warning . . . to the factory manager that if he fails to give consent he is a criminal. The vice of vagueness in criminal statutes is the treachery they conceal either in determining what persons are included or what acts are prohibited. Words which are vague and fluid . . . may be as much of a trap for the innocent as the ancient laws of Caligula. We cannot sanction taking a man by the heels for refusing to grant the permission which this Act on its face apparently gave him the right to withhold. That would be making an act criminal without fair and effective notice."

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Journal

THE FOOD AND DRUG ADMINISTRATION

Evolution of The Field Organization

By ROBERT S. ROE

Because of Inexperience, the Present Flexible Field Organization Had to Be Developed Mostly by the Trial-and-Error Method. As It Turns Out, However, This Flexibility Is a Decided Asset, Since It Permits Minor and Major Changes to Meet Changing Conditions

THE present organization of the field forces of the Food and Drug Administration is the result of many changes over the years. The enforcement of the Federal Food, Drug, and Cosmetic Act of 1938—as did that of the predecessor law, the Food and Drugs Act of 1906—depends upon the activity of the inspectors and chemists throughout the country in the inspection of factories, packing plants and distributors, the collection and analysis of samples, and various other field and laboratory investigations. The location of field laboratories and the deployment of inspectors are important factors in determining the effectiveness and efficiency of the Administration.

Investigations of the Bureau of Chemistry under Dr. Harvey W. Wiley over a period of many years prior to 1906 had disclosed widespread debasement and misrepresentation of foods and drugs. These disclosures had helped to crystallize the sentiment in Congress for the enactment of corrective federal legislation, resulting in the passage of

Mr. Roe Is the Director, Division of Program Research, Food and Drug Administration

the Act of 1906 and its assignment to the Bureau of Chemistry * for enforcement.

While the Bureau had had experience in the analysis of many foods and drugs, it had not had experience in the administration of a regulatory law of such scope as this and the conducting of investigations to gather evidence to support legal actions. The Bureau, then, was confronted with serious organizational and operational problems. Fortunately, no attempt was made to set up a permanent, rigidly defined filed organization. On a more or less trial-and-error basis, laboratories were established and inspectors assigned in various locations throughout the country. From time to time these locations were changed in an effort to improve operations, setting a pattern and policy which have been followed to the present time. Our concept of the appropriate organization of the field forces for the administration of federal regulatory statutes such as the Food, Drug, and Cosmetic Act is an organization that is flexible and can easily be altered as to territorial boundaries and personnel quotas as changes in production, manufacturing, transportation, population and other factors may dictate.

At the present time the field forces of the Food and Drug Administration are organized in districts with headquarters in 16 of the principal cities throughout the country. Each of the 16 districts is in charge of a chief, and the personnel includes chemists, inspectors and

* The Bureau of Chemistry of the United States Department of Agriculture. A reorganization within the Department of Agriculture in 1927 established the Food, Drug and Insecticide Administration (later termed the Food and Drug Administration) as the enforcement agency for the Food and Drugs Act and other regulatory laws, and the Bureau of Chemistry and Soils to which was assigned the research functions of the former Bureau of Chemistry.

In 1940, under the President's Reorganization Plan No. 4 issued under authority of the Reorganization Act of 1939, the Food and Drug Administration and most of its functions were transferred from the Department of Agriculture to the Federal Security Agency.

clerks. The districts are designated by the names of the headquarters cities. Well-equipped laboratories are maintained at district headquarters. In three of the districts—Buffalo, New Orleans and Seattle —"subdistrict" laboratories are also operated at Pittsburgh, Houston and Portland, Oregon, respectively. In all the districts, one or more resident inspection stations are established at other cities in the district territories.

At the time of the enactment of the Food and Drugs Act of 1906 there were already in operation six branch laboratories of the Bureau of Chemistry at the chief ports of entry (New York, Philadelphia, Chicago, New Orleans, Boston and San Francisco). These laboratories had been established several years before to handle examination of imports under the Act of March 1, 1899. After the enactment of the Act of 1906, additional branch laboratories were established. The annual report of the Bureau of Chemistry for 1909 shows 21 branch laboratories in operation: Boston, Buffalo, Chicago, Cincinnati, Denver, Detroit, Galveston, Honolulu, Kansas City, New Orleans, New York, Omaha, Philadelphia, Pittsburgh, Portland (Oregon), St. Louis, St. Paul, San Francisco, Savannah, Seattle and Nashville.

After a brief period of preliminary instruction and training in Washington, the newly appointed food and drug inspectors were assigned to various locations throughout the country. These inspectors operated under the instructions and supervision of the chief inspector in Washington. The branch laboratories as originally set up reported to the Division of Foods in the Bureau of Chemistry in Washington.

A reorganization occurred in 1914. The annual report of the Bureau for 1914 gives this explanation:

> To increase the efficiency of the enforcement of the food and drugs act the Bureau of Chemistry was recognized during the year. The field service of the Bureau was set off from the central organization and divided into an Eastern, a Central, and a Western District, with headquarters, respectively, in Washington, Chicago and San Francisco. A single official was placed in charge of each District. He is directly responsible to the Bureau of Chemistry for all the work in his District, so that the food and drug inspectors and the laboratories are no longer separate or independent of each other. Incident to this division of the field service of the Bureau of Chemistry, the smaller laboratories at Detroit, Kansas City, Omaha, Nashville, Pittsburgh, and Portland, Oregon, were closed.

In 1917 this reorganization was extended to create "station districts" within each of the three principal inspection districts and to place one man in charge of both laboratory and inspection work in each "station district." In establishing the "station districts" or stations,

the boundaries of the laboratory territories were adopted as the boundaries of the new stations. This provided for stations with headquarters in the following locations:

Eastern District.—Boston, Buffalo, New York, Philadelphia, Savannah, Washington, Puerto Rico.

Central District.—Chicago, Cincinnati, Minneapolis, St. Louis, New Orleans, Kansas City. (At Kansas City there was no laboratory at that time but there was an inspection office, and the importance of the area required establishment of a station.)

Western District.—Seattle, San Francisco, Denver, Honolulu.

Other Inspection Stations

At the time of the establishment of station territories, inspection stations were in operation in other cities as well as in the laboratory cities. Inspection stations were continued at Detroit, Nashville and Houston in Central District and at Los Angeles, Phoenix and Portland, Oregon, in Western District, and the chief of the Bureau commented that the scope of the territories and the nature of the inspection work might make it desirable to place additional inspectors in certain sections, with headquarters other than at station headquarters. Whether these inspectors, resident in cities other than station headquarters, should operate under direction of the station chiefs in whose territories they were located or report directly to the district chief was left to the discretion of the district chiefs.

Prior to the establishment of the stations in 1917, the boundaries of the inspection and laboratory territories were not always the same. For instance, in Western District the boundaries of the inspection territories evidently were determined primarily by railroad lines and were arranged in accordance with transportation facilities available to the inspectors stationed variously at Seattle, Portland, San Francisco, Denver, Los Angeles and Phoenix. The laboratory territories, on the other hand, followed state lines to take care of state cooperation and collaborative work, with special reference to assisting state inspectors and other officials in preparing and handling federal cases instituted by the states.

The Bureau of Chemistry orders establishing "station districts" stated that the territories of the stations were determined "primarily on the basis of hearings." This apparently contemplated that only at

the laboratories were there facilities for conducting hearings—office quarters and stenographic assistance—and that the laboratory locations were most convenient and accessible to the manufacturers and shippers in the station territories.

In 1917 the headquarters of Eastern District were transferred from Washington to New York City. Since 1917 there have been many changes in stations ("station districts") and districts.

Honolulu Station was discontinued in about 1918 and Puerto Rico Station in 1933. The work loads in these territories were relatively too low to justify continuing the stations, particularly since necessary coverage could be accomplished through cooperative arrangements with the territorial officials.

In about 1926 a laboratory was re-established at Kansas City Station to afford analytical facilities and to eliminate delays and costs involved in sending samples to other labortories. In 1931 the Los Angeles inspection office was converted to station status with the installation of a laboratory. This change was effected to enable more efficient and adequate handling of the increased work loads brought about through increasing population and manufacturing activity in that area.

In 1934 the laboratory and station headquarters located at Savannah, Georgia, were transferred to Atlanta. The station originally had been established at Savannah because of the extensive import trade at that port. A marked decrease in the importation of foodstuffs through the port of Savannah and the fact that Atlanta was a railroad center affording transportation lines to all areas in the station territory made Atlanta the preferable location.

District Boundary Lines and Transportation Lines

The reasons for some other changes are of interest. For instance, in May, 1929, transfer of a number of counties in Texas, Florida, West Virginia and Ohio was effected in order "to make district boundary lines conform more nearly to existing transportation lines." In July, 1930, changes in station boundaries affecting Kansas City, Minneapolis and Chicago Stations were based upon convenience of transportation.

Again, convenience of transportation was the reason for transferring a portion of West Virginia to Baltimore from Buffalo Station in 1932.

In 1934 another reason appears as the basis for a change in station boundaries. This involved a change in the boundary between Chicago and Cincinnati Stations in Indiana in order to bring the boundary line in conformity with the judicial district line in Indiana. To have station boundaries coincide with judicial districts was the reason for adjusting St. Louis and Minneapolis Station boundaries in Iowa in 1936.

Reasons for Substantial Changes in 1945

In 1945 substantial changes were made in the boundary lines of Chicago, St. Louis and Minneapolis Stations, involving the transfer of southern Iowa from St. Louis to Minneapolis Station, and the transfer of a portion of Wisconsin and the upper peninsula of Michigan from Minneapolis to Chicago. Several reasons were given for these changes:

(1) The dairy industry in Iowa was more or less integrated with the same industry in Minnesota and western Wisconsin, and the dairy program of the Minneapolis Station was more suited to the work in that area than was the dairy program of St. Louis Station.

(2) The change in Wisconsin eliminated the division of the eastern judicial district in that state between the two stations.

(3) Products moving in and out of the Wisconsin area involved were predominantly from and to Chicago rather than Minneapolis.

(4) The upper peninsula of Michigan could be more easily reached for the occasional necessary trips there from the eastern area of Wisconsin than from Minneapolis, and the transfer of this area placed all of the State of Michigan in Chicago Station territory.

California, Montana and Idaho Boundary Lines Changed

In 1945 a change in the boundary line between San Francisco and Los Angeles Stations in California was effected in order to save Los Angeles Station a considerable amount of nonproductive travel through desert areas. Also in 1945 the eastern portion of Montana was transferred from Denver to Seattle Station and a change was made in the boundary line between these stations in Idaho. These changes were accomplished in order to relieve each station of traversing certain desert areas and to assign to each station most of the area in Idaho that

was directly tributary to the principal shipping centers in the respective station territories.

In 1948 a major reorganization of the field service was effected. This reorganization abolished the former three inspection districts which had been set up on a geographical basis and established in Washington three functional divisions made up largely of the staffs of the former field districts. This reorganization gave greater responsibility to the 16 field stations, converting them to district status, and established the present field organization. The abolishment of a number of administrative positions made possible the assignment of additional personnel to the field districts.

In 1949 a number of changes were made in the field-district boundary lines in Pennsylvania, North Carolina, Illinois, Florida and Tennessee in order to adjust the boundary lines to coincide with judicial districts. Similarly, changes were made in 1951 in boundary lines affecting Boston, Buffalo and New York Districts in the States of Connecticut, New Jersey, New York, Ohio and West Virginia. These changes eliminated divisions in Connecticut, West Virginia and Ohio and established the boundary line in New York State along judicial district lines. This change substantially reduced the area covered by the New York District, making it essentially a metropolitan district.

Influencing Factors in Locating Field-District Boundaries

It is apparent that many factors have influenced the location of the boundaries of the field districts. These factors include inspection travel requirements, availability of transportation and roads, population distribution, location of manufacturing and distributing establishments, geographical and topographical features. It is important that district headquarters (and resident inspection stations) be so located as to minimize the necessary "nonproductive travel" of inspectors, since travel costs constitute a large item in the operating budget. It is important that district headquarters have adequate transportation and communication facilities to the various parts of the territory to enable good contacts with the traveling inspectors and to allow prompt shipment of samples to the laboratory. It is also important that district headquarters be reasonably accessible to manufacturers and shippers throughout the territory to enable them to call at headquarters for information or to respond to citations. Transportation facilities also influence or reflect the mode or direction of distribution and hence

determine to some extent the proper deployment of inspectors. That population distribution and the location of food and drug producers and manufacturers have a bearing on the location of district boundaries is obvious.

The placing of district boundaries also has been influenced by the boundaries of existing federal judicial districts. It is desirable that food and drug districts coincide with, rather than overlap, judicial districts. This has become increasingly important because the growing complexity of cases brought under the Act makes it essential that the most efficient contacts exist with United States attorneys. This obviously is furthered when contacts with a particular judicial district are conducted by one field district. For the most part, district boundary lines now coincide with judicial district lines. There are a few exceptions, however.

Cooperation with State Officials

The same considerations apply—but to a considerably lesser extent—to cooperative contacts with state officials. It is desirable to avoid division of states between field districts, but this is by no means essential. Very frequently other factors are more important.

In arriving at the present districting of the country, an effort has been made to attain a reasonably uniform distribution of work loads and responsibility between the several districts. This is considered advantageous from the standpoint of general administration and classification of employees assigned to the field service. Greater accomplishment can be realized by districts of approximately the same size in personnel and similar work loads and responsibility than by districts of widely different work loads.

The table at the end of this article shows the number of employees in various categories assigned to the districts as presently organized. It will be noted that there is a heavy work load in New York District as reflected by the personnel assignments. The territory assigned to New York District is essentialy a metropolitan area. In that area there are heavy concentrations of population, drug manufacturing establishments and imports which enhance the work load. Except for New York, the work-load distribution among the districts is reasonably even.

Adjusted Personnel Quotas

In addition to the boundary changes, there have from time to time been changes in the personnel "quotas" allotted to the districts. Such

changes have been made to meet or adjust changing work loads. This is more or less a "continuing process," as the personnel requirements of the districts continually fluctuate to some extent. Exchange or transfer of personnel between districts, particularly in the inspection category, is deliberately practiced. This is necessary to maintain well-balanced staffs in the districts, and it serves also to broaden the experience and training of the individuals. Also, the occurrence of vacancies through retirements or resignations may lead to interdistrict transfer of personnel. The retirement of a senior officer of the Administration either in Washington or in the field often leads to a chain of transfers. The Food and Drug Administration as a "career service" endeavors to maintain a promotion system based upon merit. For instance, the selection of a chief chemist for a particular district is not limited to consideration of the chemists then on the staff of that district. Rather, selection is made from all qualified chemists throughout the Administration after careful appraisal of the needs of the position and the experience, training and aptitudes of the various eligibles.

In determining the relative work loads of the districts and, hence, the appropriate allotment of chemists, inspectors and other personnel, a number of factors are involved. Some of the same factors controlling the fixing of district boundaries are involved also in measuring work loads. Population, the number of food and drug manufacturers and producers—the distribution of population and manufacturing establishments within the territory—the volume of imports, the types of commodities and the types of violations likely to be encountered have some bearing on the manpower needed in a given district to enable enforcement coverage consistent with that of the other districts.

Flexibility of Field Organization an Asset for the Future

It can be expected that new developments in the future—population and industry shifts, new commodities, changes in production and manufacturing techniques and procedures, transportation changes—will dictate the advisability of further adjustments in the field organization involving district boundaries, the location of laboratories and inspection stations, and personnel quotas. The type of flexible field organization developed by the Food and Drug Administration readily permits minor or major changes to meet changing conditions. This type of field organization seems much more suitable as a vehicle for effective enforcement teams than would an organization rigidly defined by inflexible boundaries such as state lines.

Field Personnel by Districts Actual Staffing as of July 1, 1952

District	Administrative	Inspectors	Chemists	Wharf Examiners	Laboratory Helpers	Clerks	Total
Atlanta	1	10	6	..	2	5	24
Baltimore	2	14	7	1	2	6	32
Boston	2	12	8	1	2	6	31
Buffalo	1	10	9	1	3	5	29
Chicago	3	21	13	1	3	10	51
Cincinnati	2	14	11	..	2	8	37
Denver	1	9	6	..	2	4	22
Kansas City	1	12	6	..	2	4	25
Los Angeles	2	18	9	..	2	7	38
Minneapolis	2	13	6	..	2	5	28
New Orleans	2	10	9	..	3	7	31
New York	6	26	27	11	6	22	98
Philadelphia	2	15	11	1	2	6	37
St. Louis	2	14	11	..	2	7	36
San Francisco	2	13	13	1	3	5	37
Seattle	2	15	8	..	2	5	32
Total	33	226	160	17	40	112	588

[The End]

• FDA's MONTHLY REPORT OF SEIZURES •

A permanent injunction to stop further shipments of a cancer-diagnosis kit has been ordered by Federal Judge Philip L. Sullivan in Chicago, according to a report issued on November 25 by the Food and Drug Administration of the Federal Security Agency. The manufacturer did not contest the court order.

Dr. Gordon Granger, FDA medical officer, said that the government's charges that the kit is worthless were confirmed by tests of the product made by the M. D. Anderson Hospital of Houston. Tests were made on more than 100 known cancer patients and healthy medical students. Negative and positive results were obtained with both groups and, when the same individuals were retested, different results were obtained. A Houston physician did a series of tests on 30 patients, with results following the same pattern.

The FDA report also lists 24 criminal actions terminated in the federal courts on October, and the penalties levied for violation of the Federal Food, Drug, and Cosmetic Act.

Nearly 850,000 pounds of unfit foods were removed from the market in October in 88 seizure actions, FDA reported. Sixty other food seizures were based on short weight, failure to meet official standards, and debasement with cheaper ingredients. Predominant in the latter group were oysters with added water, which resulted in 27 seizures.

Fourteen drugs and devices were seized because they failed to meet labeled composition or were misbranded with misleading therapeutic claims. The remaining seizures involved a shampoo "plus egg" that would have furnished 1/180 egg for each shampoo, and a poisonous bowl cleaner that was not labeled with the warnings required by the Caustic Poison Act.

METHODOLOGY

By HENRY A. LEPPER

The President of the Association of Official Agricultural Chemists Presented Observations on Methods of Analysis and Their Relation to a Successful Regulatory Program in His Address Before the Annual Meeting of the Society Held on September 29 and 30, and October 1, 1952, in Washington, D. C.

ACCORDING to the program before us we are here attending the sixty-sixth annual meeting of the Association of Official Agricultural Chemists. In the parlance familiar to so many of us, this is a misbranding. Our association is older than the implied 66 years. This failure of perfect accord is not serious, however, as the inception of the association in 1884 makes it but two years older. The close agreement of the numeral on the program and the real age shows the importance with which our predecessors and our members, during the years, have considered the perfection of methods. Once each year was not regarded as too frequent to meet to keep the methods abreast of latest scientific developments, many of which have been the result of researches of individual members of the association. This seriousness of purpose to keep the methods up to date is evidenced by the fact that it required events of no less magnitude than world wars to cause three annual meeting to be called off during our history. Through all the years our association has held steadfast to its heritage of dedication as quoted from its first constitution: "To secure uniformity and accuracy in methods and results of analysis." Thus it has become a society of scientific achievement. It even fulfills what appears lately to have become a test of a true scientific society and that is the continued publication and support of a scientific journal otherwise insolvent.

It is no small honor to be accorded the presidency of such a scientific body. It would be untruthful not to admit the pleasure

experienced on being so chosen. With me, the appreciation of the honor bestowed was accompanied by contemplations not so pleasant, namely, the recognition of an obligation to be fulfilled and the realization of time's imprint.

I realized middle age was upon me, for in our association rarely, if ever, is it the privilege of youth to become president. Middle age has been defined by a glib-tongued radio commentator as "that time of life when you think you will feel better tomorrow than you do today but you don't." The passage of time is not without its compensations, for it provides experiences to draw on to meet that obligation which brings me before you today—this presidental address.

Author's Introduction to Association

The first knowledge that there was an A. O. A. C. came to me when I began the study of quantitative analysis. My chemistry professor was Dr. Charles E. Munroe who had taught chemistry while at Harvard University to a man who needs no introduction here, Dr. Harvey W. Wiley. They became close friends. Dr. Munroe was outspoken in his admiration for Dr. Wiley and the work he was doing. It was not strange, therefore, that his students were required to obtain a copy of the Bureau of Chemistry Bulletin No. 107 for use as a supplemental text. The impressive title, "Provisional and Official Methods of Analysis of the Association of Official Agricultural Chemists," promised a wealth of analytical methods which to us at that time was more than fulfilled by the text. I well recall our disappointment over the completeness of the book. Apparently, procedures had been perfected for all important foods and determinations. To us, with the narrow vision of those just at the doorstep of the profession, the question arose as to what opportunity could there be for further research and method development. It was several years later when it was learned that such fears were entirely too pessimistic.

My first real experience with the methods of the association came shortly after I was appointed as an assistant chemist in the Bureau of Chemistry. It was my privilege to be assigned to work with Dr. Paul B. Dunbar who, by that time, had contributed numerous methods useful in law enforcement. He was the association's referee on fruit products. The call to an administrative career, then already begun, left him little time for active work at the chemist's bench. He asked me if I wished to study methods for fruit acids with him. He stated that the Schmidt-Hiepe method for tartaric, citric and malic acids

on page 80 of Bulletin 107 was worthless and more accurate and specific methods were needed. The shock of this surprise was reflected in my question: "What, a method in that book, Doctor?" I soon learned there was nothing unusual about the replacement of outmoded methods by those based on the latest developments and improvements in analytical procedures. From that incident of my initiation into the workings of the A. O. A. C., I have devoted much of my active career to the problem of methods, and its various ramifications. I propose, therefore, to draw on this experience to offer observations which may be helpful to the continued progress and prosperity of our association and the service rendered by it to the continuing successful enforcement of regulatory laws.

It is not my premise that our activities are devoted to the development of methods solely of regulatory application. The history of the association shows that it has also served in the perfection of methods designed for research in agricultural chemistry. These two objectives provide no basis for sharp demarcation between the many methods. Each field of activity profits by and draws from the other. It is my purpose, however, to limit my remarks to the regulatory aspects of our methods.

Analyst's Evidence and Testimony in Establishment of Prima Facie Case

Most of the laws with which the majority of us are concerned require objective evidence for successful enforcement. It is the analyst who, as a result of his examination, testifies as to composition, presence of constituents or ingredients, or other factors significant in the application of the provisions of the law. Where interpretation is necessary to prove the violation, either he or another scientist depends upon the experience and knowledge obtained by a study of the composition of authentic materials. Without such evidence and testimony, failure is most likely on the first obligation of the prosecution, that is, the establishment of a prima-facie case.

The principles of practice in American courts do not favor the use of methods which carry a suspicion of secrecy or can be challenged as untried. This does not mean that there are not exceptional circumstances where methods employed must remain secret until the trial. The courts recognize when there is merit in such situations. However, in a number of cases, judges have commented adversely when publicity had not been given methods in advance of their use in

support of a case. Generally, no comment on this feature is included in the formal opinion of the court. There is one exception which will be discussed later. It is in cases where violation may be avoided by analysis before the goods are brought within the jurisdiction of the law or where analysis is made to fulfill labeling requirements that the methods of regulatory control should be available to those who are in such need of them. It is the right of the individual to be furnished methods by which his product is to be judged. But it is far more important that the method give correct results in the hands of competent analysts. Unless the methods have been tried and proven in this latter respect, their use by the prosecution must inevitably face a charge of unreasonableness.

Obligations in Choice and Use of Enforcement Methods

I recognize with you that there is nothing new in these thoughts. They are as old as our association and involve the fundamentals which led to its inception. They bear repetition to educate our younger members and to remind others of the obligations to be faced in the choice and use of methods in enforcement. It might appear that such reminder is not needed, but, frankly, I recall when expediency too often has led to the attitude that "it is only A. O. A. C. work" as an excuse for setting aside investigations on the development of methods. Methods adequate to meet the demands of jurisprudence are paramount to the work of the enforcement team of scientists, inspectors and administrative officials. Methods have been called the tools of enforcement. Our association is the workshop wherein they are patterned, molded, machined and sharpened into effective instruments. Its functions were summarized by Commissioner C. W. Crawford in his address before us last year (*Journal of the Association of Official Agricultural Chemists,* Volume 35, page 37) when he said: "This Association has established itself throughout its history of 67 years as a forum wherein all concerned may, in an atmosphere free from influences other than those of purely scientific approach, achieve the common goal—the selection of workable and serviceable methods to maintain the safety and wholesomeness and integrity of the nation's supplies of such vital commodities as its food and drugs." To this I wish to add my humble belief that were there not an A. O. A. C., there would have to be devised some form of organization or some means as yet obscure for accomplishing its functions.

With proceedings in courts involving cases brought under regulatory laws, the important part played by the evidence furnished by methods has been in many instances the subject of discussion by judges in decisions and charges to the juries. The record of federal cases shows that time and again judges have dealt in great detail with the results and interpretations of analytical evidence. Victory for enforcement far exceeds defeats. This no doubt is also true of state cases. The failure to also cite state records is not because of any lack of appreciation of the importance of our methods to state law enforcement but the decisions on cases under the federal food laws happen to be readily available in one compilation and there is a limit to the time to be spent, even for the preparation of a presidential address.

It is notable that, with few exceptions, in none of the decisions is it mentioned that the methods were those of the A. O. A. C., nor is the association referred to, although those of us familiar with the details know that frequently such was the case. In fact, I have been present in court on numerous occasions where the prestige of the association was a factor in the weight of the evidence supplied by its methods. The opposition is quick to capitalize on the lack of association recognition of methods employed in any case. One case which had its humorous side was the first contest involving the use of the Fitelson test for tea seed oil as an adulterant of olive oil. The contest on a seizure came up before opportunity was found to study the method collaboratively. In an attempt to support the accuracy of the test, I was called upon to give evidence of the successful outcome of my independent study of the method. During the cross-examination the opposing lawyer tried to make much over the fact that the A. O. A. C. has not adopted the method. I explained there had been no meeting of the association since the method had been perfected and hence no opportunity to adopt it. I went on to assure the counsel that at the next meeting the association would—and at this point the judge in no uncertain terms warned me not to attempt to be a prophet in his court. Little did he realize the accuracy with which such a prediction could be made, and in spite of his admonition the association did adopt the method at its next meeting. We won the case.

Specific Reference to Association in Frozen-Egg Case

There were two cases, at least, where the judges referred specifically to the association. By coincidence, they were both on eggs and both were lost. One was a prosecution on a shipment of frozen eggs. The

evidence to support the charge of decomposition was based solely on the smell test. In his decision the judge referred to certain facts, disclosed in the evidence and of which he said he had knowledge, which he could not overlook in deciding if the government had sustained the burden of establishing its case beyond a reasonable doubt. One of these facts stated was: "I do know that for years chemists have been seeking more efficient and rigid methods for the determination of the presence of decomposition in eggs. One need only study the reports of the Association of Official Agricultural Chemists to become aware of this effort. (See *Journal of the Association of Official Agricultural Chemists,* Volume 20, page 159 (1937); Volume 21, page 179 (1938); Volume 22, page 298 (1939); Volume 24, pages 119, 319 (1941).) In most of these studies, representatives of the Food and Drug Administration participated either as referees or associate referees. It is difficult for me to believe that if the organoleptic test is as efficient as plaintiff's witnesses say that such complete and consistent efforts were being made by the chemists to acquire rapidity in their processes."

Another Decision, with Evidence Resting on Bacteriological and Chemical Results

The other case was a contested seizure of dried eggs charged as being decomposed. In that case the evidence rested on bacteriological and chemical results. In his decision the judge quoted from the above quotation in the frozen-egg case down to the word "effort" and then went on to say: "The tests upon which the government here relied were developed in secret. The experimenters did not disclose the methods used in their tests or their conclusions either to the Association of Official Agricultural Chemists or to any other scientific society. Furthermore, they did not announce these tests or their conclusions to the industry. They were 'sprung' on the claimant herein and apparently in one other similar action tried about the same time. [I should like to interject at this point that the other similar action resulted in a favorable decision for the government.] In view of the long efforts to try to attain some reliable standards, it would have been only fair to all concerned for such tests and conclusions to have been disclosed to the industry so that an opportunity would have been afforded to verify them, or to determine whether the arbitrary limits stated by the department were proper conclusions to be drawn from the tests. This is especially true as all decomposition and

fermentation in foods is not undesirable. Roquefort and other cheeses, and sauerkraut are examples.

"The high bacteria count for the authentic pack indicated in the Government tests resulted only when good eggs were contaminated and held at an 85° temperature for 18 hours or more. The evidence discloses that the claimant herein followed no such practice. It used fresh, current receipt eggs which had been inspected by candling. They were kept at an ideal temperature up to the time when they were dried. This positive testimony offsets the expert opinion of the government witness which was based upon an experiment which was never submitted to the Association of Official Agricultural Chemists or to other learned scientific societies."

Significance of Mention of Association

Although the work of our association and its methods did not contribute to victory in these cases, their mention has a significance to us. In the frozen-egg case, there is the implication that had scientific evidence been presented based on investigations reported by members of this association in support of testimony of the government witnesses on the significance of the smell of the eggs, it would have been adequate to overcome the contradictory testimony of experienced egg dealers that the eggs did not have the odor of decomposition. In the dried-egg case, the court, by citation from the text of the court in the other case, recognized the potential weight of scientific evidence. His quarrel was with what he called the secrecy under which the methods were held. Thus did the court, in the formal opinion, lightly dismiss the preponderance of evidence furnished by the analytical results, so that the testimony of the claimant as to his practices carried more weight. The important factors in the case were more simply summarized at the close of the trial when it was said that although the government's scientific evidence was unrefuted, the man who made the dried eggs testified that nothing happened to them and the court had to believe him. The reference to the A. O. A. C. in this case might imply that had the methods been adopted by our association, the outcome might have been different. On this we can only speculate, but we can take the reference as a recognition of the association as the authoritative scientific body for the establishment of methods of regulatory application. The lesson to be learned from these two cases is that the activities of our association should be so

conducted as to prevent opportunism from citing it or its work to the detriment of law enforcement.

The responsibility for successfully carrying on the work of the association rests largely on the referees, including associate referees, and the collaborators. Nothing is to be gained here by repetition of the suggestions, instructions and recommendations for increased efficiency in referee activity, which have been offered in addresses and reports at annual meetings from time to time. However, all who are sincerely interested in carrying this work forward, from the most experienced to the most recently appointed referee, can profit by reading in the pages of our journal from the writings of Doolittle (Volume 8, page 229 (1925)), E. M. Bailey (Volume 17, page 42 (1934)), and Reindollar (Volume 28, page 38 (1954)), to mention those I now recall who have made contributions of special helpfulness.

It is not intended to chide or criticize, but even as outstanding as the progress has been, there are still opportunities for improvement. Year after year one serious handicap to our work is the lateness with which too many referees submit reports. Procrastination is often the reason. Another reason is that unless the need for the method is in the nature of an emergency, other duties are often regarded as more pressing and allowed to take precedence over work on methods. Both causes can be avoided by systematic planning of the work and allocation of time to be devoted to it. The studies projected each year are never academic. They are of practical application to the needs of today or the demands of tomorrow. Some pressing problems are only those of tomorrow because of lack of methods to handle them today. Every regulatory official has the responsibility to help provide adequate methods to meet all the needs. Wherever methods are wanting, enforcement will stagnate.

Book of Methods

While we may take pride in the size of our *Book of Methods,* may I say that that in itself presents a sizeable problem. Through various economies with space, we have been able to keep the methods within the bounds of one volume. Business principles dictate that this be continued if possible. Some referees, but not all, take advantage of the cross-reference system used in the book and thus save space through adaptation of available methods to new problems. It has been suggested that a post in the nature of a director of referees or co-ordinator of methods be established. Duties would be to bring

the methods into closer co-ordination during the years of development and adoptions between revisions of the *Book of Methods*. As an example, there are numerous opportunities to unify directions differing not in fundamentals, but only in wording. An important function this official might perform would be to serve as a clearing house in advance of changes in methods in one chapter in such cases where they serve other chapters by cross reference, to provide ample opportunity to the other referees concerned to determine the applicability of the changes or provide other more suitable directions. It is believed that referees would welcome assistance and guidance in some of these responsibilities. According to our two-year rule for adoptions, the position should be created this year if it is to be helpful for the eighth revision of the *Book of Methods*.

Collaborative Studies Discussed

This association was the first, or certainly among the first, to use collaborative studies on analytical methods to demonstrate concordance and reproducibility of results. Concordant results on like samples show that the directions that have been studied are adequate, clear and instructive and that their techniques are sound, workable and specific. The referees do not always realize that the directions demonstrated by collaborative tests to have these attributes constitute the wording which merits adoption. Attempts at revision after the study should be avoided, because what is being adopted is the written word collaboratively proven to be adequate to carry all essential instructions. There is no assurance that the same acceptable collaboratice results will be obtained by revised directions. The referee should perfect the wording in a precise, clear, expository form before asking collaborative assistance. If revisions are later found to be desirable, the method should be restudied.

The question as to who should be collaborators is of major importance. I have said that the methods must give reproducible results in the hands of competent analysts. Collaborators must not be chosen or assigned without regard to qualifications or background. Many good methods have failed of adoption or their acceptance has been too long postponed because of poor results obtained by one or more inexperienced analysts during a collaborative study. From their very nature, our methods may not be workable by the neophite or novice in analytical chemistry. On the other hand, they should not require the skills of those of outstanding analytical expertness. There appears

to be a happy middle ground. Each collaborator should be one whose results would be accepted as correct when obtained with current methods on the same level of difficulty.

Methods and Their Relation to Successful Regulation—A Summary

It has been my aim to present several observations on methods and their relation to a successful regulatory program. What I think they show can be summarized by a few remarks. Methods in a vast majority of trials supply the essential proof. There are well-defined and established requirements that methods must meet to stand the test of scrutiny applied in the courts. Methods development, perfection and modernization should not be left to the will, moods and scientific curiosity of the laboratory worker. Every organization having laws to enforce which require the use of analytical methods should provide in its regulatory program for a project on methods development. The time allotted to such work should be in proper perspective to the overall needs of the service. Having been provided, only emergencies of serious threat to the public should curtail that time. Certainly, methods work is as important as routine case development. Enforcement activities have been likened to a hare-and-hound relationship. Violators take the jump and enforcement officials chase and follow. When one is apprehended, there is always another in the offing. New and better methods will always be needed. To the extent that methods fail or are wanting, to that extent does the enforcement official begin to go out of business. **[The End]**

• MISREPRESENTATION •

Beverage concentrates . . . A company engaged in the sale of a beverage concentrate has agreed to desist from representing by drawings of grapes that the products, their color or flavor are derived chiefly from the natural juice of the grape. (Released December 5, 1952.)

Yogurt . . . A seller of yogurt is charged with falsely representing in advertisements that the proteins in yogurt are in predigested form, that proteins and minerals in yogurt are more easily assimilable, and that milk nutrients in yogurt are more easily absorbed by the blood, and that the casein or albumin of cow's milk fermented with yogurt culture are transformed into more highly digestible forms. (Complaint issued November 25, 1952; released December 8, 1952.)

Cosmetic preparations . . . Discontinuance of representations that respondent's hair preparation is not a hair lacquer or plastic and is superior to other wave-setting lotions—except those having water as the solvent—in reducing the drying time of hair has been agreed to in a stipulation. (Released December 10, 1952.)—CCH TRADE REGULATION REPORTS, ¶ 16,640; ¶ 11,267; ¶ 16,642.

The Consuming Public

By BENJAMIN F. STAPLETON, Jr.

In This Paper, Presented at the Annual Meeting of the ABA's Division of Food, Drug and Cosmetic Law on September 17, the Author Alleges that the FDA Has Attempted to Protect the Consuming Public Far Beyond the Intentions of Congress

SINCE THE ENACTMENT of the first food and drug laws in this country, the overriding policy considerations extolled first by Congress, second by the Food and Drug Administration and last by the courts have been the protection of the consuming public from the physical and economic effects of the dishonest, fraudulent or careless food manufacturer. It adds little to say that these policy considerations were unanimously shared by legitimate manufacturers, distributors and retailers of food products. Without the full cooperation of the food industry, the great advances in the enactment, enforcement and administration of the food laws would have been impossible.

Both the economic cheat and the manufacturers of adulterated food products have had their day in court. Our courts, guided first by the 1906 Act and later by the 1938 Act, have firmly and finally cast such minor segments of the food industry out of the market places of our nation. These decisions the Food and Drug Administration, the food industry and the public had every right to expect. The food and drug laws were given by the courts the teeth that were to make the Acts powerful forces in the public interest. The Food and Drug Administration, in the flush of these victories, has attempted to legislate by judicial decision far beyond the boundaries of the 1938 Act as intended by Congress.

Perhaps no other decision gave the Food and Drug Administration more encouragement to push on to new frontiers in the law than

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the *Sullivan* case.[1] In 1948 the Supreme Court in the *Sullivan* case, by devious legal gymnastics which still remain unconvincing, strained every rationale to grant to the Food and Drug Administration power which that agency believed it needed. The *Sullivan* case is such a landmark in food and drug law that a review of that decision is superfluous here.

Although the *Imitation Jam* case [2] was initiated before the decision of the Supreme Court in the *Sullivan* case was handed down, nevertheless the impetus of the Court's philosophy in the food and drug field as exemplified in the *Sullivan* case gave FDA much hope for a successful conclusion in the *Jam* case. Much has been written of the *Jam* decision. It would, therefore, serve no useful purpose to again discuss that decision at length.

But to this writer the *Jam* decision had a twofold effect. First of all, it clearly told the Food and Drug Administration that there was at long last a limit to the expansion of the 1938 Act by judicial amendment. Prior to the *Jam* decision, FDA, with some judicial support, believed that there was no end to the expanding interpretations of the 1938 Act. The Court, however, in the *Jam* case said, through Mr. Justice Frankfurter, that the imitations section of the Act was placed there in clear and unmistakable language and that language would be given effect even though it varied from the desires of the Food and Drug Administration.

In reaching the decision, the Court was guided by the economic implications of the outlawing of imitation jam. The questions asked of counsel during oral argument indicated the importance attached

[1] *U. S. v. Sullivan*, 332 U. S. 689 (1948).

[2] *62 Cases Jam, etc. et al. v. U. S.*, CCH FOOD DRUG COSMETICS LAW REPORTS ¶ 7193, 340 U. S. 593.

to this phase of the case.[3] The Court decided, in effect, that they were not going to eliminate from the market place an imitation jam which was sanctioned by Congress and which the consuming public purchased at a lower price than the pure fruit preserve.

Second, the consuming public was acknowledged to have the intelligence to read a label marked "imitation jam" and understand that they were not getting the pure fruit preserves. It was indeed a reaffirmation of the modest intelligence of the consuming public.

The critics of the *Jam* decision were quick to cry out in alarm that reliance on truthful labeling was not enough to protect the consuming public.[4] They say that the American people are not intelligent enough and that American business is so dishonest that the consuming public will be grossly deceived.

Just how intelligent or unintelligent is the consuming public? Must we draft our laws and regulations to protect the average member of our consuming public or must such laws and regulations be drafted to protect the last most ignorant, mentally retarded purchaser in the market place? Must all the purchasers who are a little below average, average, and above average in intelligence suffer for the mental deficiencies, carelessness or indifference of that last segment of our society?

I was astonished and shocked, as obviously were counsel for General Foods Corporation, to find that FDA thought "perhaps 40% of the population are on the below-average side." And yet, over the signature of the Honorable Phillip B. Perlman, Solicitor General of the United States, on behalf of the Food and Drug Administration, appears that surprising statement at page 10 of his petition for a writ of certiorari in the case of *U. S. v. 88 Cases, etc. "Bireley's Orange Beverage,"* No. 274, October Term, 1951, cert. den. 72 S. Ct. 88. I do not believe, and it would be difficult to convince me otherwise, that 40 per cent of the American citizens are so mentally retarded as to be unable to rely on their own intelligence in the purchase of food products. If Mr. Perlman's estimate is correct, it is in itself a shocking indictment of our educational system, our medical profession and, most of all, an indictment of our American way of life which, in our institutional advertising at least, we cherish so highly. If 40 per cent of the con-

[3] 19 *United States Law Weekly* 3239, and following.

[4] See "The Practical Effects of the Jam Case Decision," by Daniel R. Forbes, 7 FOOD DRUG COSMETIC LAW JOURNAL 178 (1952), and "The Imitation Jam Case —Some Implications," by Charles M. Fistere, 7 FOOD DRUG COSMETIC LAW JOURNAL 165 (1952).

suming public is so mentally deficient, it will take much more drastic laws than have even been considered by FDA. The success of the food laws in themselves repudiates Mr. Perlman's estimate of American incompetence. The food laws of our country have been successful because of, and not in spite of, the mentality of our citizenry.

Bireley Case Examined

The depths, in the opinion of the Food and Drug Administration, to which the intelligence of the American public has fallen (or perhaps out of which depths such citizens have never arisen) is clearly indicated by the seizures of Bireley's Orange Beverage. An examination of the *Bireley* case is therefore in order.[5]

Bireley's drink is a noncarbonated, orange-flavored drink derived from a beverage base or concentrated orange juice, sugar, orange oil, citric or lactic acid and United States certified colors. The colors were added to give the product a more pleasant commercial appeal.

In the early days of Bireley's orange drink, the beverage base was used primarily by dairies and the principal distribution was by dairies to stores and householders along with milk. This product was marketed in the conventional-type quart milk bottle. Later manufacture and distribution was along the style of the conventional cola-type soft drink.

The government seized Bireley's Orange Beverage marketed in quart-size dairy bottles in 1945 as an "economic adulteration" under Section 402 (b) (4) of the Act in that "yellow coal tar dyes were mixed with the product to make it look like a product composed or in large part of a fresh orange juice and thus better and of greater value than it is" and "it consists of a mixture of a small quantity of concentrated citrus juice or juices and water, to which have been added additional water, in excess of that contained in the fresh juices from which the concentrates were made, sugar, lactic acid and orange oil, which substances so added to the said food increase the bulk thereof and give it the taste and odor of an orange juice or of a beverage containing a large quantity of an orange juice, thereby making the said food appear better and of greater value than it is."

In effect, the government's position was that if the beverage "looks like" orange juice and is not, in fact, orange juice or "in large

[5] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7199, 187 F. (2d) 967, cert. den., 72 S. Ct. 88.

part" orange juice, it cannot be sold under any circumstances, no matter how clearly labeled.

A large portion of the government's case revolved around the contention that the product resembled orange juice and many mothers purchasing it were apt to purchase it to feed to their children as orange juice in order to give them necessary vitamin C contained in orange juice. The government laid great stress on the fact that lack of vitamin C in a child's diet for a long period would cause scurvy.

The jury in the district court rendered a verdict for the government that the beverage was adulterated. Thus, at this point in the litigation, the government's test case had pushed the concept of economic adulteration to a new frontier.

Among the many instructions to the jury by the trial judge that made a verdict for the government almost a foregone conclusion was the tenth request of the government, namely, that the jury's function was "to determine whether *any part* of the public, the vast multitudes, which includes the ignorant, the unthinking and the credulous, and those who do not stop to analyze in making a purchase would be so misled." (Italics supplied.)

It is this charge to the jury upon which the court of appeals laid great stress. It is this charge upon which this paper is based.

Author's Interpretation of Basic Philosophy Behind Charge to Jury

To my mind, the charge had a basic philosophy behind it which is repugnant to our concept of doing business, the rights of our citizens and, in a very real sense, our American way of life. It exemplifies a step of FDA to push the 1938 Act far beyond the intention of Congress at the time of its enactment. True, the Supreme Court had given some indications of the extent to which it would force its interpretations of the Act in the interest of the consuming public. The *Quaker Oats*[6] and the *Sullivan* cases are examples of the friendly attitude of the Court toward FDA.

The *Jam* decision was, however, the signpost which said there are limits to how far the Court will go in accepting the arguments and philosophy of FDA. As Mr. Justice Jackson stated in the *Jam* arguments, in an attempt to come to the rescue of Mr. Robert Stein, special assistant to the Attorney General, who was under considerable verbal barrage from Mr. Justice Frankfurter:

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[6] *Federal Security Administration v. Quaker Oats Company*, 318 U. S. 218.

I will come to his rescue. If the Court uses loose language, counsel has a right to throw it back at us.[7]

Nothing could be more illuminating on the extent to which the brakes were put on FDA's interpretation of the *Quaker Oats* case than the oral arguments in the *Jam* case. On the basis of little more than the excess verbiage in the *Quaker Oats* case, the FDA attempted to outlaw imitation jam. And as Mr. Justice Frankfurter said to the government attorney, after voluntarily allowing the government 30 minutes to present its case without questioning from him:

Now that my time is up I want to get Quaker Oats out of this case. Quaker Oats has nothing to do with this case (*Imitation Jam*).[8]

The attempted extension of the Act by FDA was curbed by the *Jam* case. The FDA was due for another shock in the *Bireley* case.

In the *Bireley* case we, as lawyers, can imagine the ease with which laymen and laywomen on a jury in the face of the charge (No. 10) could find that some part (any part) of the consuming public would be misled. As General Foods pointed out in their brief on appeal, if the jury considered that last segment of our population that cannot read or write or those who would be considered as deficient mentally, the question would more aptly be put: "In what marketing situation under the Food and Drug Act would this segment of the consuming public *not* be misled?"

The tenth charge to the jury brings up the fundamental question under the 1938 Act: Who is to be protected by the operation of the Act? If the Act were intended to protect all consumers, including the very last segment of our society, which is mentally incompetent, such segments of our society are literally being protected at the expense of every other person purchasing in our market places. If Congress intended such a result, as evidently the trial court believed in the *Bireley* case, FDA is considerably behind in its enforcement program. It should forthwith ban all trade-name foods, abolish the grading of food products and eventually forbid advertising of foods entirely. FDA would then ideally sanction the sale of canned corn in a yellow can with no label except the word "corn"; peas might be marketed in green cans, etc. Such an interpretation of the 1938 Act is absurd. And yet the tenth charge to the jury in the *Bireley* case stated that the jury should find the General Foods Company guilty of adulteration if *any* segment of our society would be misled.

[7] Publication cited, footnote 3, at p. 3242. [8] Publication cited, footnote 3, at p. 3241.

In prosecuting their action against Bireley's Orange Beverage, FDA was able to find two consumers who testified that they had bought an orange-flavored drink believing that it was orange juice. That FDA was able to find two such witnesses is certainly a tribute to the investigation and research facilities of the Food and Drug Administration. Their very presence in court was no more amazing than the testimony that they gave. One witness was produced who testified that she was a mother of five children and had finished the ninth grade in school. When one of her daughters was six weeks old her physician advised her to feed the child orange juice. The mother, in carrying out this order, fed her daughter four ounces of Bireley's Orange Beverage a day from the time she was six weeks old until her illness when she was seven months old. These four ounces were delivered from a quart bottle containing Bireley's Orange, which quart container was shared by all the other members of the family, including the mother herself.

The witness further informed the jury that she purchased Bireley's to save time and money and that it cost her "in the 20's" for a quart bottle. To make matters even more convincing, the hospital records indicate that the mother had given the child orange juice two months before the admission to the hospital but that the child refused it and so was not encouraged.

To fortify this testimony, the government put on another housewife and mother. This witness began feeding three ounces of the beverage to her daughter from the age of two months until she became ill. She, too, had been advised by her doctor to feed the infant orange juice, and she was meticulously carrying out the doctor's instructions. The witness, who had eight years of schooling, stated that she bought the drink in the quart milk bottle for reasons of economy. For a quart of this beverage she paid 18 or 19 cents. We should remember that it would take approximately 16 oranges to derive a quart of orange juice. Even in 1940 it would be incredible for any housewife to believe that she could purchase 16 oranges for 18 or 19 cents.

The testimony of the witnesses was the foundation of the government's case. It is true that over claimant's objections the government was allowed to introduce into evidence surveys taken by interns, nurses and nurse's aides at or in connection with maternity wards in hospitals or well-baby or prenatal clinics. These surveys were made pursuant to forms prepared by the Food and Drug Administration. They were objected to by the claimant on grounds that they were

taken under highly prejudicial circumstances and that the surveys themselves were inadmissible as hearsay because claimant did not have the opportunity to cross-examine the persons surveyed. The court of appeals, in considering the *Bireley* case on appeal, approved the admissibility of these surveys. At the same time that the government filed its petition of certiorari, the claimant filed a cross-petition in an attempt to obtain review by the Supreme Court of the affirmation by the court of appeals of the admissibility of the surveys. The Supreme Court denied both the petition and cross-petition in 72 S. Ct. 88.

The government contended in its brief in the court of appeals [9] that even if the surveys were improperly admitted, there was adequate evidence to support a judgment for condemnation. In support of this argument, the government again gave great emphasis to the testimony of the two mothers, and it was undoubtedly their testimony that had a profound effect upon the jury.

Certainly their testimony represents the ignorant, unthinking, credulous segment of the public which does not stop to think in making a purchase. It is submitted that the two witnesses were so incredibly ignorant or emotionally upset at the time that it is doubtful whether they could ever have arrived at the correct solution to any marketing problem. But under the tenth charge, the jury had no other alternative except to render a verdict for the government that the food product was adulterated under Section 402 (b) (4) of the Act.

Implications of Charge

If the charge to the jury was a correct one, it is submitted that FDA would have dictatorial powers over the food industry, and if FDA so desired, we would all be slaves to their most autocratic pronouncements. It would be difficult indeed to imagine any food product which could not be proved to be adulterated by the production of such witnesses as those that appeared for the government in the *Bireley* case.

Such a charge, however, would be clearly contrary to the standards of "the reasonable man" etc., which runs through so many other portions of our civil and criminal law.

The question resolves itself then into this form: "To whom must the Bireley's orange appear to be of better and of greater value than it

[9] Libellant's brief, pp. 30-32.

is?" Section 403 (f) sets up the answer to that question in unmistakeable language as follows:

> Sec. 403. A food shall be deemed to be misbranded— . . . (f) If any word, statement, or other information required . . . to appear on the label . . . is not prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

It is not the reaction of all the consumers, or the most ignorant or credulous, that is the test; it is the reaction of "the ordinary individual under customary conditions of purchase and use." As further stated in *U. S. v. 62 Packages of Marmola Prescription Tablets*,[10] the test is whether or not a substantial portion of the literate purchasing public has been deceived.

The problems of "to whom must the food appear better than it is" and how is it to be determined whether the food "appears better than it is" received major consideration in the *Bireley* case on appeal by the Court of Appeals for the Third Circuit.[11]

The court of appeals held that the trial court's charging that a deceptive appearance to "any part" of the public sufficed and then underlining the significance of "any part" by reference to "the ignorant, the unthinking and the credulous" was in error.

The correct standard, said the court of appeals, was "the reaction of the ordinary consumer under such circumstances as attended retail distribution of the product." The court rejected the thought that Congress contemplated the reaction of a person who is savant or dolt. The court of appeals then referred to the standard set forth in Section 403 (f) and concluded that it would be unreasonable to place an abnormal and more burdensome standard as a test for Section 402 (b) (4) merely because Congress did not deem it necessary to specify a test.

Although the government filed its petition for certiorari in the Supreme Court and the claimant its cross-petition for review of the admissibility of the surveys, both the petition and cross-petition were denied. On June 30, 1952, an order was entered in the United States District Court for the District of New Jersey dismissing the libel with the consent of the government and the General Foods Corporation. The balance of the 88 cases of Bireley's Orange have been returned to the claimant and destroyed. The claimant now distributes his prod-

[10] 48 F. Supp. 878 (1943).

[11] Cited at footnote 5.

uct solely in the conventional cola-type bottle, and should the government attempt another test case, it must be brought on the basis of seizure of the cola-type bottles.

Why does the *Bireley* case seem so important a milestone in food and drug law? To this writer it is, together with the decision in the *Imitation Jam* case, a curb upon the attempt of the FDA to legislate into the law by judicial decision legal concepts which were and are wholly foreign to those intended by Congress in 1938.

Evaluation of Administration's Position in *Bireley*

The position of FDA in the *Bireley* case was certainly most drastic, unduly burdensome and revolutionary. It was so abnormal that it is reasonable to conclude that the tenth charge was presented to the court as a bargaining point to modify the language of any instruction presented by the claimant. Having no basis in law, certainly the inclusion of the charge to the jury must have been as much a surprise to the government as it was a shock to the claimant. But once the charge was accepted by the court, obviously the government was anxious to exploit it to the end.

The very proposal of such a charge for the jury, however, reveals the thinking of the FDA. It indicates an attempt to abandon the traditional standard of the ordinary consumer. If it had not been checked in such an affirmative fashion, the lengths to which it could, and possibly would, have been carried are indeed staggering. If the tests of governmental thinking were to be based on the reaction of the illiterate, the senile, the infants, the mental patients and even, as General Foods Corporation pointed out to the Supreme Court, the animal kingdom which eats food and is treated with medicaments covered by the Act, then, indeed, such protection would be at the direct expense of the ordinary consumer and the manufacturer and producer of wholesome, reliable food products.

In a year in which much emphasis is being placed upon state government undertaking constructive programs without the aid of the federal government, corporations engaged in the production and distribution of food products can well follow such an example. Private business should not request or encourage the radical departures by FDA from the fundamental concepts of the food and drug laws. Indeed, we should be vigilant in our demands that FDA stay within the basic confines of the 1938 Act or, in the alternative, request Congress

to consider such departures in the form of Congressional amendments to the Act.

Comments Not a Criticism of Food and Drug Administration

The above is not meant as criticism of FDA. The Administration has accomplished so very much throughout the last 50 years that none of us could in good conscience give them anything but our heartfelt thanks. It remains a maxim of political science, however, that governments and their administrative agencies by natural inclination desire to spread their activities further and further into the activities of private business, on the theory that private initiative either has no desire or is incapable of working out for itself any of its own problems. The Food and Drug Administration is no exception to such a trend, and the food industry should not be a party nor lend encouragement to such a program.

There are many ills in the food field which we must recognize and which FDA does a magnificent job of correcting, thus rendering invaluable service to the American public. There will always be the dishonest, fraudulent manufacturer who will attempt to place economic "cheats" on the market. There will always be dangerously adulterated products, either adulterated deliberately or by carelessness in production methods. There will always be new products, if America is to remain virile, to be examined and tested before they are presented to the consuming public. In all these matters the Food and Drug Administration plays an all-important role and one for which the American people, if properly informed, should be eternally grateful.

Where Would Authority End?

Success, however, can easily invite a distorted view of the role to be played by the FDA. Surely, Bireley's Orange Beverage was no threat to the health or pocketbook of the average member of the consuming public. It is an integral part of the soft-drink industry which evidently is a source of delight to millions of our fellow Americans. If a product such as Bireley's Orange Beverage can be seized and denied the avenues of interstate commerce, where would the authority of FDA end? Without the sympathetic, intelligent and nearly always realistic Administration now handling this most important segment of our governmental life, the possible end result could indeed be appalling.

[The End]

Five Years of Oyster Standards of Identity

I SHALL LIMIT my talk today primarily to the subject of standards of identity for fresh raw oysters. Standards for sizes of fresh raw oysters exist, and there are also standards for canned oysters, but those are not a part of today's talk.

The federal food and drug law provides for the establishment of standards of identity, quality and fill of container for any food whenever in the judgment of the Administrator of the Federal Security Agency such action will promote honesty and fair dealing in the interest of the consumer. This authority is applied primarily to products which are peculiarly susceptible to sophistication and adulteration. Such procedure affords the maximum of opportunity for the protection of the consumer.

Water is one of the long-profit adulterants frequently encountered in foods, and the nature of fresh raw oysters plus the methods of preparation and handling make them particularly vulnerable to the practice of substituting water for oysters and reaping profit at a rate that represents the difference in cost of these two articles. It would seem that the judgment of the Administrator in establishing standards of identity for raw oysters, with a view to limiting their added water content, is wise and consistent with the intent of the Congress.

Standards are not established by administrative fiat. As most of you are well aware, the standard-making procedure involves adequate notice to interested parties, lengthy hearings and the establishment of a complete record of testimony, from which no one who has anything real to contribute can be excluded. The subsequent standard or order must be based upon the substantial evidence of that record. After the establishment and publication of such standard, any aggrieved party has the right of appeal to the circuit courts of appeal of the

By JOHN L. HARVEY

The Author Read His Paper at a Meeting of the Oyster Institute of North America in Atlantic City Last Month. He is an Associate Commissioner of the FDA

United States. When such appeals are sustained, the court has authority to remand to the Administrator for further proceedings or to set aside the rule. When a standard has survived all due process, it is a part of the United States laws to the same extent and with the same force as if it were established by act of Congress. The standard of identity for fresh raw oysters is supported by very exhaustive evidence.

The adulteration of fresh oysters with water occurs in a number of different ways. Excessive water in the soaking pots will be taken up and cause the oysters to be adulterated. Excessive length of time in soaking tanks or in soaking and blowing will increase the water content. Allowing water to remain after washing, or improper drainage, produces adulteration with water. Last, there is deliberate and direct addition of fresh water to oysters that are otherwise properly prepared. Producing raw oysters in compliance with the standard is designed to, and will, avoid adulteration by any of these means.

It is also true that free liquid in excess of 5 per cent, determined 15 minutes after preparation, causes fresh oysters to be in violation of the standard. It is to be emphasized, however, that free liquor is not the only measure of violation by reason of added water, and oysters may be adulterated from excessive soaking even though the free-liquid content is within the 5 per cent allowed by the standard. On the free-liquor question you doubtless have heard arguments that oysters will exude some of the free liquid, even though they have been prepared in accordance with the standard, and such exuding of free liquor may cause a violation of the 5 per cent figure.

It may be of interest to you to know that the Food and Drug Administration has made a thorough study to establish the facts with regard to this point. We can conclusively prove that oysters originating in the Chesapeake Bay area will not bleed or leak, so that the free liquid increases during standing, handling or shipping. These studies are not casual but are extensive, and the conclusions are overwhelming. In no single case did we find authentically packed oysters in good condition subject to bleeding or leaking as a result of storage. Actually, within 15 minutes of packing, such oysters absorbed or took up some of the free liquid that was present. These studies were carried on under conditions stipulated in court and should settle forever the question of bleeding of Chesapeake Bay oysters.

Another established fact about fresh raw oysters that may be of interest is that when packed with excess free liquid they tend to arrive at a state of equilibrium within the first 24 hours after packing, and from then on the ratio between the free liquid and the oysters is relatively stable, unless the oysters are frozen or decomposition sets in.

I'd like to give you something in the nature of a report of the regulatory activities of the Food and Drug Administration on fresh raw oysters since the standard became effective.

After the standard became effective and during the calendar years 1947, 1948 and 1949, we undertook to carry on an extensive educational program with the oyster packers. This program included sanitary inspections, with observations of the procedures being employed, and a discussion of any faulty procedures observed with the oyster shuckers and the shippers. Seizures during this period were very limited and involved only aggravated cases. No criminal prosecutions or injunctions were recommended before the year 1949.

During 1949 we instituted a limited seizure program with a more extensive factory-inspection program, and this was continued through 1950. During those two calendar years, we instituted a total of 23 seizures on shipments of watered oysters and 11 criminal prosecutions against shippers were referred to the courts. During the same period we applied for and obtained five injunctions which placed a restraint, under penalties for contempt of court, for the shipment of adulterated material by the five firms enjoined.

In the 1951-1952 season we instituted an intensive seizure campaign which was closely correlated with factory inspections and

the collection of official samples. During that period we examined samples from 272 lots, representing as many shipments of Chesapeake Bay oysters. Included in these were 149 lots of oysters regarded as actionable, and the product of 59 different plants was investigated. The program resulted in 93 separate seizures covering about 21,646 pints of oysters, which were valued at approximately $16,000. During that period four prosecutions were presented to the courts and two petitions for injunction were filed. These are still pending before the courts.

Methods and Procedures in Developing Evidence of Watering

It may also be of interest to some of you to be informed as to the methods and procedures which are employed in developing evidence on added water.

Whenever, in the course of factory inspection, it is evident that excess soaking at any stage of the manufacturing process or improper drainage is occurring, inspectors promptly undertake the preparation of a so-called authentic pack. In preparing such packs, inspectors employ the oysters that are in use by the firm at the time of the inspection. Every detail of the packing process of the authentic pack is closely supervised, so that the ultimate two gallons of oysters packed by the inspectors are not exposed to water beyond the 30-minute limit allowed by the standard. The oysters used in this pack are drained on a standard skimmer, as specified in the standard, and are packed into pint containers exactly in accordance with the procedure employed in the plant. One gallon of the oysters of such pack is redrained within 15 minutes, and a free-liquid determination is made by the inspectors. The other gallon of the pack is submitted to the laboratory, either the mobile trailer laboratory operating in the field or to an established laboratory, such as at Baltimore or other district. In the laboratories, analysis is made for free liquid, for salt and for total solids. This is the authentic-pack feature of the inspection.

During the inspection, inspectors also collect two gallons of oysters which were packed by the management prior to the time of the arrival of the inspectors. One gallon of these oysters is examined on the spot by the inspectors for free liquid, and the other gallon is submitted to the laboratory for the same examinations as are made on the comparable authentic sample.

Whenever practicable, official samples are collected from shipments of oysters prepared while the inspectors were present. When

this is not possible, samples are collected from stocks available, and a reinspection is made to bracket shipments of oysters made in the interim, that is to say, samples are obtained which will represent material packed both before and after shipments which may be regarded as actionable.

Evidence which supports our seizure recommendations is the information gathered at factory inspection, correlated with the laboratory samples of authentic packs and compared with results obtained on the laboratory examinations of official samples. This procedure affords opportunity to make direct comparison between oysters packed according to the standard in the particular packing house with those packed by management and shipped in interstate commerce. This affords the advantage that the adulteration is not judged against the general average of oysters but directly against unwatered oysters from the same source.

FDA's Program for the Future

Perhaps it will be helpful to you for me to express some views as to the future operations of the Food and Drug Administration as they relate to adulteration of oysters.

It is only fair for me to say to you that we intend to vigorously enforce the standards, because we feel it is in the best interest of the consumer. We expect to enforce these standards through the various legal sanctions that are provided in the law, that is to say, we expect to continue making seizures where justified, to petition for injunction where deemed necessary and to criminally prosecute where violations occur.

The rather extensive seizures have brought up the question as to the salvage that may be employed, if any. Adulterated oysters containing excessive water cannot be salvaged by draining. We will sanction release under appropriate bond after the entry of decree in accordance with the law, with a provision for manufacturing into a food product wherein oysters and water are normal ingredients, such as oyster soup and oyster stew, whenever it seems to us and to the court that such a course is a proper one. We will not obligate ourselves to assist violators in obtaining as much salvage as possible where the evidence is clear that violations are deliberate and repetitious.

In the foregoing remarks I have undertaken to stress the fact that the adulteration of oysters with water is a cheat and a fraud upon

the consumer and that the concern of the Food and Drug Administration about the widespread abuses that exist in the industry is because of our obligation to protect the interests of the American consumer. I think I should add, however, that I am strongly convinced that thorough and efficient enforcement of the standard to prevent adulteration with water is also in the interest of the industry.

I think it is well known that buying practices and price structure in the industry are in a somewhat chaotic state, largely because the price that a packing house can afford to pay for oysters is influenced by the amount of water that it expects to add before selling them to the consumer. The watering of oysters not only cheats the consumer by selling him water at the price of oysters but also gives him a product with a deteriorated flavor, somewhat changed physical characteristics and much less desirable eating qualities generally. The oysters become chalky-white and bloated, with soft, spongy tissues, and lose their rich creamy-yellow color and firm texture. On cooking, watered oysters rapidly diminish in size and the meat becomes tough and almost devoid of taste. This kind of product is not that for which the consumer is willing to continue to pay a fancy price. He expects something better, and it is inevitable that the sale of such debased products as oysters will go a long way toward killing off the oyster industry. The high cost of oysters to the packer cannot be compensated for by watering the product that is sold to the consumer, if the industry expects to long survive and remain prosperous.

It is a fact that many oyster packers do not yield to the temptation to add water, because they are honest and do not wish to violate the law and also because they recognize that it spoils the oysters and ultimately will spoil the oyster business. It is equally true that many, whom I believe to be very short-sighted, do yield to the temptation and do thereby increase immediate profits, but the ultimate result is chaos in the industry and conditions that are assuredly adverse to long-continued prosperity.

It is true that the combined efforts of the state and federal food and drug organizations cannot be made sufficient to apprehend every shipment of adulterated oysters. It is equally true, however, that to the extent that we find possible, taking into account the numerous other problems of adulteration and misbranding which confront us, we shall endeavor to keep the pressure on, and we believe that in doing so the oyster industry, as well as the public, will be benefited.

[The End]

ENFORCEMENT OF

The Oleomargarine Amendment

This Paper Was Read at a Meeting of the Association of Food and Drug Officials of the Southern States in St. Petersburg, Florida, on June 19, 1951. The Author Hopes to See More Cooperation Among Federal, State and Local Agencies in the Enforcement of Their Respective Oleomargarine Laws

CONGRESS in the Eighty-first Session enacted H. R. 2023, an act to regulate oleomargarine, to repeal certain taxes relating to oleomargarine and for other purposes. In repealing the taxes of oleomargarine, Congress also amended the Food, Drug, and Cosmetic Act. In doing so, Congress declared that the sale or the serving in public eating places of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine originates from an interstate source or from the state in which it is sold.

This amendment became effective on July 1, 1950. It prohibits the sale or offering for sale of colored margarine unless it is packaged. It limits packages of colored margarine for sale in retail establishments to one pound or less. It requires the word "oleomargarine" or "margarine" to be printed on the label of the package in type or lettering at least as large as any other type or lettering used on the label. It requires all ingredients in the product to be stated on the label. It requires each part or parts of the retail package contained in a wrapper to bear the word "oleomargarine" or "margarine" in type of not less than 20 point. It prohibits the serving of colored oleomargarine by a public eating place or its possession in a form ready for serving, unless a notice stating that margarine is served is displayed prominently

By E. C. BOUDREAUX

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and conspicuously in such place and manner that it is likely to be read and understood by the ordinary consumer, or is printed or otherwise set forth on the menu in type not smaller than that normally used to designate other food items. It requires that yellow margarine served in public eating places be in triangular shape or be identified as margarine or oleomargarine by the labeling. It defines colored margarine or oleomargarine as having a tint or shade containing more than 1.6 degrees of yellow, or yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent. An exceedingly light tint, barely distinguishable from white, is enough to classify margarine as colored. The amendment reiterates the prohibition already in law against use of filthy, putrid or decomposed raw materials.

In carrying out the work under this amendment, we have essentially the following responsibilities: to inspect and regulate oleomargarine manufacturing plants and firms supplying them with raw materials in order to insure that only clean, wholesome and otherwise unadulteraed raw materials are used. During the past year, inspections have been made of all oleomargarine plants, and there is in progress at the present time an inspection program dealing particularly with firms preparing crude oils which eventually find their way into the manufacture of oleomargarine. When inspecting oleomargarine plants, we check on sanitation, raw materials and labeling. We also obtain information concerning the distribution of the product, since this may later prove helpful in detecting improper diversion. No doubt our biggest job is in connection with the serving of colored

oleomargarine by eating establishments. In 1945 there were 525,000 public eating establishments in the United States, and in New Orleans District alone there were 33,700. No doubt the number of such establishments has increased considerably since that date.

Amendment's Enforcement in Public Eating Places

In the enforcement of the amendment, insofar as public eating places are concerned, there is a decided change from our experiences in the past. Most of our previous work has dealt with products which are distributed in wholesale channels. It was realized when this law was passed that we would be dealing with firms that have little or no experience with the federal enforcement of the food and drug law. Therefore, the early stages of our operations were largely educational. The degree of compliance to be expected would depend on how well the operators of public eating places understand and are willing to conform to the requirements of the law. Trade journals have been very helpful in spreading this information, but many operators of public eating places are not subscribers. The National Association of Margarine Manufacturers was very helpful in distributing information to public eating establishments and, as early as June, 1950, had prepared and was distributing a yellow leaflet entitled "Here's What You'll Need to Know About the New Federal Law on Serving Yellow Margarine." This leaflet not only explains the requirements of the federal act but also furnishes some information concerning the requirements of the various states. At that time, 17 states prohibited the sale of yellow oleomargarine in eating places, but since that date several of these laws have been repealed.

Unfortunately there was a delay in setting up the appropriation, and we could not begin active inspections of public eating establishments for several months after the law became effective. However, considerable educational effort had been carried on through talks given by members of the Administration. As our inspectors visited the restaurants, they determined in short time whether proper signs or menu declarations existed and whether the spread was served in triangular pieces or, if not in triangular pieces, whether the servings were oleomargarine and identified as such. Upon introducing himself, the inspector explained the purpose of the visit and, after making the necessary observations, if violations were encountered, explained in detail to the management the requirements of the act and handed

him an imformative leaflet. In these discussions every effort is made to allay the fears and suspicions which often arise in the mind of the individual being interviewed by a government employee and to give a clear and concise explanation of the purpose of the visit and, where desired, details of the law being enforced.

Generally speaking, where violations are noted on the first visit, follow-up is planned within a reasonable time to determine whether the educational effect of the first visit has borne fruit. While it is felt in the early stages of the enforcement that prosecutions would not ordinarily be based on violative conditions noted during first visits, as this work progresses we can expect that it will not be necessary to continually educate the public eating places. We can therefore expect that some prosecutions will be based on evidence obtained during initial visits. As we go along there will be less and less need for educational work. Various states and local agencies interested in food and drug law enforcement have shown splendid interest in this amendment. Not only have they continued their enforcement operations where local laws and ordinances existed, but they have cooperated extensively with us both from the standpoint of educating the restaurants and from the standpoint of assisting us in connection with detecting violations. A number of large cities and several states have duplicated the educational notice which the Food and Drug Administration prepared, and through their inspectors have brought this amendment to the attention of restaurants in their localities. One state has a case underway involving prosecution of a firm which was bootlegging oleomargarine as butter. Another state has just completed a prosecution case against a public eating place for violating the state margarine law.

You will be interested in some of our experiences under this act thus far, particularly from the standpoint of public eating establishments. Through May 31, 1951, a total of 19,936 inspections of public eating places were made throughout the country. It is estimated that as of June 30, approximately 22,000 such inspections will have been made. Through May 31, 4,053 places were in violation. The highest incidences of violation through May 31 were in West Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Arkansas, Missouri, Kansas, Oklahoma, Utah, Arizona and New Hampshire. We consider as a violation of the amendment not only the serving of patties of oleomargarine without signs or menu declara-

tion but also its undeclared use as a spread on toast, potatoes, waffles, etc. I have asked some of the other districts to relate to me some of their experiences. Thus far, on the basis of reports from the food and drug districts, it appears that there exists from approximately 1 to 35 per cent violations on the part of establishments at the time of the second visit. This means that they have continued to be in violation, even though the requirements have been fully explained to them during the first visit. Some of the districts have already issued citations, and, in a limited number of instances, prosecutions have been recommended.

One district has encountered very little activity in the serving of colored oleomargarine, since this is prohibited by four states in its territory and the fifth state assesses taxes of 20 cents per pound. Several districts report very active enforcement by states in their territory of state laws similar to the federal amendment. For example, Michigan recently passed such a law, and Illinois expects to pass one which will probably take effect when the prohibition against colored oleomargarine is repealed July 1.[1] Recent efforts to repeal the New York State law prohibiting the sale of colored oleomargarine were not successful.[2] In New Orleans District no states prohibit the sale or serving of colored oleomargarine. Some of them require signs. You may be interested in the fact that as of May 31 we inspected 1,646 establishments and found 615 in violation in our territory. About 16 per cent of the firms which were in violation originally and were revisited were found to be still in violation. We have already issued citations to a number of the firms still in violation. The violations encountered range from total violations to some omission, such as failure to have sign or menu declaration, or failure to serve in triangular form or identify the serving if in square form.

Amusing Occurrences

Some amusing incidents have been reported. In one instance, the inspector reported that the lady in charge of the restaurant was trying to cook meals, serve them and take care of three children, all at the same time, as well as comply with the oleomargarine regulations. She was not doing a good job on any of these things. In another case, the inspector tried to get the proprietor to sign an affidavit setting

[1] [Editor's Note: Illinois passed H. B. 52, effective July 1, 1951, which is similar to the federal law.]

[2] [Editor's Note: New York enacted Ch. 97, effective July 1, 1952, which is similar to the federal law.]

forth the violative conditions under which he was operating. The proprietor said: "My mother may have raised some foolish children, but I am not one of them." In another case, the inspector found the restaurant serving oleomargarine without a sign or menu declaration. He went to get his camera to photograph this condition and when he returned found the proprietor in the act of putting up the signs which had been hidden behind the cash register. In another case, a woman proprietor realized her visitor was a food and drug inspector, became completely noncooperative and would not let the inspector take a sample from patties that were ready to be served. She claimed that the patties were not ready to be served. She tried to give the inspector a sample of butter which she claimed they were serving. In some instances, oleomargarine patties and butter patties are being mixed. In still another case, the inspector found the firm to be cutting patties into triangles but not breaking them apart. When an inspector visited a suburban lunch counter in Portland, Oregon, the woman proprietor stated emphatically that she used nothing but butter because she was raised on a farm, but, at the next restaurant the inspector visited, the proprietor stated just as emphatically that she used nothing but oleomargarine because she was raised on a farm.

I believe that enforcement work under this amendment can be carried along smoothly without a great deal of difficulty. We appreciate very much the cooperative efforts on the part of states and cities. Incidental to other operations, they can reach many public eating establishments more rapidly than we can with our limited inspectional staff. Also, many of these states and cities have local ordinances or state laws dealing with oleomargarine. We have found that where there has been any laxity in the enforcement of the state law, there are by far a greater number of violations than would be the case where the state law had been effectively enforced in prior years. I sincerely hope that those states which have laws will become as active as possible in their enforcement. I believe that active enforcement on the part of both the federal and state governments, supplemented with what work the cities can do, will make the job easier for all of us. I believe that a well-coordinated program, planned in advance if possible, will avoid much duplication. I would like to throw out to each of the states the thought that perhaps we could do more mutual planning on this and other projects and afford the taxpayer better protection, perhaps at lower cost. **[The End]**

The Grain Sanitation Program

The Author, Deputy Commissioner of Food and Drugs, Federal Security Agency, Finds Himself Well Satisfied with Progress in the Program to Date. This Paper Was Read at the National Meeting of the Grain and Feed Dealers Association in Minneapolis on September 9

IN DISCUSSING the grain sanitation program which is being conducted as a cooperative enterprise by the grain trade and the governmental agencies involved, a brief history of the events leading to its inauguration is in order.

National, state and city pure food laws have been concerned with sanitation since the beginning of this century. In 1938, Congress, after five years of study, enacted a new federal food and drug law which placed much greater emphasis upon sanitation. This law provided in essence that foods to be legal for interstate shipment must be free from filth and must not be prepared, packed or held under insanitary conditions whereby they may become contaminated with filth. In other words, the aim of the statute is to require that foods be clean and that the environment in which they are held before delivery to the consumer shall be such as to insure the cleanliness of the finished product.

These provisions relate to dairy products, poultry, spices, nuts, fishery products and the whole gamut of foods, including grains and the human foods made from them.

At the time of the passage of this law, the country was suffering from a financial recession. Many industries and many individual firms were concerned about their financial condition. Economy was widely practiced. This had an adverse effect upon sanitation, because the economies included smaller expenditures for normal plant maintenance. It was not possible for the Food and Drug Administration, with its limited facilities, to begin simultaneous sanitation programs covering

By GEORGE P. LARRICK

all of the wide variety of food products involved. It was necessary to begin with some industries and, as improvements occurred, to expand the program into other areas.

The first fields covered involved, largely, products which are eaten without further cooking in the home. This was because sanitation has the greatest relation to public health where the filth is consumed without cooking. Examples of articles in these categories are candy, all bakery products and some fishery products such as crab meat.

It was recognized at that time that the cereal-food industries could improve their sanitation practices. A start was made in the baking industry and in the other cereal-food industries such as those that prepare macaroni and breakfast foods.

All of these programs were undertaken by first acquainting the leaders in the industries with the objectives sought and thus acquiring as much voluntary compliance as possible. Inspection of bakeries at that time showed that hundreds of them did not give enough attention to sanitation. We found that rats and mice, as well as a variety of cereal insects, were living and reproducing in some bakeries. Quite naturally they defiled the foods with which they came in contact.

During the course of this program, a number of legal actions were filed in the federal courts, but, once top management became aware of the insanitary conditions that prevailed, many industries did not wait for the government to require them to clean up, but they took the ball themselves and ran with it. The American Institute of Baking, for example, organized a division whose principal concern

is sanitation. It employs inspectors who are skilled in bakery sanitation. This industry improved its facilities, designed new machinery that is more easily cleaned and took many other steps to improve housekeeping and sanitation. Today it has the right to be proud of the progress that has been made.

When this state of affairs was reached in the baking industry, we could release the chemists and inspectors who had been engaged in inspecting plants and analyzing bakery goods, so that the next step in the program could be taken.

Pilot inspections were made of representative flour mills. Here, again, conditions were found which led to the contamination of flour with insects and the excreta of rodents. We sought opportunities to meet with top management in the milling industry. Mr. Herman Fakler was the key industry representative in what later became a spendid example of industry-government cooperation. He arranged for us to meet on various occasions with the board of directors of the Millers National Federation, and we were invited to appear on the program of its national convention. The pattern which we have described in relation to the baking industry repeated itself.

Cooperation from Top Management in Industry

The top management of the milling industry concerned itself with sanitation. A number of mill executives told us later that they had not been aware of the need for scrutiny of their sanitation and housekeeping practices. They had left these details to subordinates, and the subordinates had been preoccupied with problems of production, particularly at a time when a recession was followed by a war, competent manpower was scarce and materials for normal plant maintenance were scarce and sometimes almost impossible to obtain. Nevertheless, when top management gave personal attention to the problems, they were solved. Here, again, improvements had to be made. The milling industry got the best technical advice available on how to deal adequately with rodents and insects. We congratulate its members upon the progress they have made, because today, with some few exceptions, the mills themselves do not contribute filth to flour.

In spite of the happy situation which developed in both the baking and milling industry, it was obvious that flour and finished bakery goods were still not yet as free from filth as is desirable and practicable. It became evident that the grain itself was not clean.

The Food and Drug Administration recognized that the problem of cleaning up grain was indeed a large one. We had only the most general idea of how large the problem was and what could reasonably be expected of the grain trade in the matter of improvement. We deliberately set about to learn just what the problem was. We met with the board of directors of the Millers National Federation and discussed the problem with them. We asked that they recommend to their members that they join with us in a survey of a year's duration designed to determine just how much filth there is in wheat and to what extent present-day milling machinery removes this filth. We sought and received the advice and help of the grain trade and the Department of Agriculture in planning this investigation.

The mills were listed, and a careful selection was made to obtain mills representing various categories as to size, type of cleaning and milling equipment, and other important factors. Once every two weeks during the summer and once every month during the winter, mills in this group were visited by our inspectors and a complete sanitary inspection was made. This was done to assure ourselves that any filth found in the finished flour had not been contributed in the mill but was, in fact, coming from the grain. In addition to the sanitary inspection, samples of the uncleaned wheat were taken, and this wheat was followed through the milling process. Another group of over 100 mills was selected at random by proven sampling procedure. Carloads of grain arriving at these mills and classed by the mills as of milling quality were obtained every month during the 12-month survey. All of these samples were carefully analyzed. The results of this survey are reported in a 50-page technical document which the Food and Drug Administration has published and which the industry has reproduced and distributed widely.

Some Conclusions Based on Survey

Some of the conclusions are important for the purpose of this discussion:

(1) Large quantities of wheat are contaminated with insects and with their excreta.

(2) Large quantities of wheat are contaminated with rodent excreta.

(3) Present-day milling machinery does not remove this filth during the milling process. It takes out some but it leaves substantial quantities.

There are other incidental sanitation problems such as those caused by birds having access to grain.

It is obvious that if we are to have clean cereal foods, the objective must be to keep the filth out rather than to try to clean the wheat after it has become contaminated.

We believed from the beginning that if the facts were made known to the grain trade, they would join with us in a program to keep grain clean. A start was made some three years ago when Mr. Bowden invited us to appear on the program of this association. A grain sanitation committee headed by Joe Gregg became active at that time, and the work of that committee has continued and grown ever since.

Realism at the Production and Storage Levels

Let me say at this point that no one recognized more than we in the Food and Drug Administration that if a program of improved sanitation in the grain industry was to be a success, we must have the cooperation and active help of those who produce and handle grain. We recognize that to obtain this sort of cooperation we must so conduct ourselves as to deserve it. The program must be realistic. It must not demand the impossible. It must not basically disrupt the economic structure of the grain trade. In other words, the program must be one which reasonable men who produce and store grain can enthusiastically endorse and support. We needed the help of the leaders in the grain industry in developing such a program. We think we know how to enforce the pure food and drug law since most of us have been at it for more than a quarter of a century, but there were—and still are—many facts about the grain business that have a vital bearing on the production and marketing of grain where our knowledge was limited indeed.

We are glad to report to you that we have had the help of your leaders. Details of the program which we proposed have been modified from time to time to meet, realistically, problems that have been pointed out to us.

Probably most of you are familiar with the details of the program as it is now in operation. The first step required a great deal of publicity aimed at elevator operators and the grain farmers. We want everybody who is interested to know what the program is and what the objectives are. Following this extensive distribution of information, inspectors of the Food and Drug Administration began spot checks of elevators to see whether or not improvements were being made.

The initial inspections are designed to be educational and to further disseminate information concerning how to deal with insects and rodents. The authoritative information concerning the solution of these problems was provided by the Bureau of Entomology and Plant Quarantine of the Department of Agriculture and by the Fish and Wildlife Service of the Department of the Interior. Their representatives are on the program to explain in more detail the important contributions they have made and are making.

As we have said, the first inspections are largely educational. The inspectors point out to the elevator operators conditions observed which, in the opinion of the inspectors, are likely to cause the grain to become contaminated. Of course, if an elevator is found so bad that no reasonable man would tolerate the insanitary conditions involved, no period of grace can be allowed and contaminated grain from such an elevator is subject to action forthwith.

I am glad to report to you that this condition is rare. Taking a hundred inspections at random, a great many firms were found to have provided adequate sanitation procedures. Many others were in process of doing the things necessary to put their houses in order. A few were planning to make the changes but were a little dilatory in beginning until after the inspector arrived. Only one man out of the hundred expressed hostility to the program, and his sentiments were that people had been eating ground up bugs and rodent manure in the past and he did not see any reason why they should not continue to do so in the future. This man, at the time of the inspection, was deliberately mixing wheat that was obviously grossly contaminated with insects with new wheat and thus seeking to dilute the filth. We, of course, suggested to our field representatives that they proceed against shipments from this elevator.

The second phase of this program involves the examination of wheat on the market for rodent filth. When the inspector finds that

a representative sample from a lot of grain is substantially contaminated with rodent filth, that grain should not be used for human food but should be diverted to animal feed. Our obligation is to see that this occurs.

It was originally planned that during this crop year samples of wheat would be taken at random from interstate shipments and examined for insect infestation and if substantial infestation was found the product would be subject to action.

Intensive Educational Campaign Suggested by Grain-Trade Representatives

Representatives of the grain trade pointed out to us that more progress toward the objective of clean wheat could be made if the industry and the government were, during this crop year, to conduct an intensive educational campaign directed at the farm level to acquaint farmers with the steps that should be taken to keep grain clean.

During the course of our survey we had found that our men could take a representative sample of wheat, mix it and withdraw a subsample of one-quarter pint, and then examine this sample for insect emergence holes. We found that, by and large, if this one-quarter pint contained three grains with emergence holes, there were in that one-quarter pint approximately 15 internal insects that had not as yet emerged. We hoped that this method could be adopted by farmers and country elevators so that each could know the sanitary quality of the grain and whether or not it was suitable for human use.

The trade pointed out that it would be virtually impossible to disseminate this information and educate thousands of country elevator operators and hundreds of thousands of wheat growers to use the method immediately, and this industry offered to undertake a very extensive program to acquaint farmers with the means of keeping the grain clean. Its leaders convinced us that greater progress would be made toward our common objective if we postponed that part of the program until the next crop year, which begins in July, 1953. The industry also offered to sponsor research designed to perfect simpler and quicker methods of judging the grain.

We are glad to report that the Manhattan Laboratories of the Division of Stored Product Insect Investigations of the Bureau of Entomology and Plant Quarantine have already published one method which appears to be very promising.

The necessity for an additional examination of your grain beyond the United States grade determination creates some practical problems for you. While we do not pretend to have the practical knowledge of your business which would be required to solve these problems completely for you, we have seen many food industries pass through similar periods of development, and it may be that the experiences of some of the industries will be helpful to you.

For example, one of the things that worries your country warehousemen is the possibility of an unscrupulous farmer trying to pass off infested wheat as new wheat during the harvest rush. This situation closely parallels that of the creamery operator who cannot examine carefully every can of cream delivered to him every day and yet has the responsibility of using only clean cream in the manufacture of butter. One practice which the dairy industry evolved to solve the problem was to have the creamery employ a field man to visit the dairy farms. The field man tells the farmer how to take care of his cream in order to get top price for it and, at the same time, reports back to the creamery on any individual who cannot or will not cooperate, so that this individual's cream can be examined more carefully. This practice has been of value to progressive producers as well as to the dairy industry.

Suggestion for Application of Experience of Other Industries to Present Situation

Another aspect of the same thing which worries you is the prospect of having to make a more thorough examination of incoming grain when trucks are already lined up for perhaps a mile waiting their turn at the scales. This reminds us of the plight of the tomato cannery or ketchup plant, where long lines of trucks full of tomatoes form during the harvest glut. The entire tomato crop, as you know, matures in a short period and must be handled expeditiously to avoid heavy losses from spoilage. Tomatoes must be examined for maturity, color, amount of decay, blemishes and other factors. In order to expedite these examinations, many canners have set up inspection stations some distance from the canning plants for the convenience of truckers as well as plant management.

Truckloads of tomatoes which are not of the quality desired or which for any reason must be given special handling may thus be

diverted for such handling immediately, and loads which are acceptable can be taken care of much more promptly upon arrival at the plant.

Without belaboring the point, I believe the similarity of these examples to the situation which confronts you is close enough at least to warrant consideration as idea material. There are, of course, others which we will be glad to discuss with you if you think such experiences hold any promise in your particular situation.

Summary of Phases 1 and 2

Now I would like to summarize again the difference between phase 1 and phase 2 of the enforcement program and the present status of each.

Phase 1, which began in May and is continuing, is the elevator-inspection phase. Any court actions brought under this phase will allege that the grain involved was held in a warehouse which we inspected and found to be contributing insect, rodent or bird filth to the grain.

Under phase 2, elevator inspections will not be the primary method of operation, but carloads of grain will be sampled at random and court action taken against filthy grain. Under this phase we have made a distinction between rodent filth and insect filth. The part relating to insect infestation has been postponed for the present crop year, as I stated earlier. However, sampling of carloads of grain for rat and mouse pellets has already begun, and we are glad to be able to say that there has been unanimous agreement that the rodent-filth part of this phase should not be delayed.

We in the government are very well satisfied with the progress this program has made to date. We are convinced that it is moving rapidly in the direction of cleaner grain. Our purpose will be to continue to try to deserve the cooperation which you have so generously extended. Although we will have to bring some regulatory pressure, our objective is to bring the fewest legal actions that are necessary to keep the program moving forward. We do not expect a miracle to happen. We do not expect instantaneous correction of sanitation problems, but we know that if you and we continue to work together that within the next few years the grain supply of the United States will be so clean that all of us will have cause to be proud. Grain is food—keep it clean! **[The End]**

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